NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA UK LIMITED and ASTRAZENECA PHARMACEUTICALS LP,	CIVIL ACTION NO. 08-3237 (MLC)
Plaintiffs,	**MEMORANDUM OPINION**
v.	
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,	
Defendants.	

COOPER, District Judge

Defendants, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's") move for summary judgment of noninfringement of United States Patent No. 5,482,963 ("'963 patent"), owned by Plaintiffs, AstraZeneca UK Limited and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca"). Dr. Reddy's contends that though its Zafirlukast Tablets are equivalent to the '963 patent, the doctrine of prosecution history estoppel precludes AstraZeneca's infringement claim under the doctrine of equivalents. AstraZeneca cross-moves for summary judgment on the issue of prosecution history estoppel, arguing that because it surrendered no equivalents during the prosecution of the '963 patent, prosecution history estoppel is inapplicable. For the reasons set forth below, the Court holds that AstraZeneca is estopped from invoking the doctrine of equivalents, and thus Dr. Reddy's Zafirlukast Tablets do not infringe the '963 patent.

I. Background

A. ANDA Process

This action arises under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271, 282), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) (collectively, the "Hatch-Waxman Act").[1] Sale of a new drug is prohibited without approval from the United States Food and Drug Administration ("FDA"). 21 U.S.C. § 355(a). To obtain approval, a pioneering manufacturer must file a new drug application ("NDA") containing clinical studies of the drug's safety and efficacy. 21 U.S.C. § 355(b)(1). The manufacturer must also identify all patents that claim the drug or a method of use. 21 U.S.C. § 355(b)(1)(G). The FDA publishes a list of drugs and the applicable patents in its Approved Drug Products With Therapeutic Equivalence Evaluations, known as the "Orange Book." Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., 601 F.3d 1359, 1361 (Fed. Cir. 2010).

A manufacturer seeking to market a generic copy of these listed drugs may submit an abbreviated NDA ("ANDA"). 21 U.S.C. §

[1] The Court is guided by the format used by the United States Court of Appeals for the Federal Circuit in citing the Hatch-Waxman Act. See, e.g., Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353, 1355 (Fed. Cir. 2008).

355(j). The ANDA process streamlines FDA approval by allowing the generic manufacturer to rely on the safety and efficacy studies of a drug already listed in the Orange Book upon a showing of bioequivalence. 21 U.S.C. § 355(j)(2)(A)(iv). As part of the ANDA process, a generic manufacturer must certify one of four statements concerning the applicable listed drug: (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug ("Paragraph IV"). 21 U.S.C. § 355(j)(2)(A)(vii).

The Hatch-Waxman Act facilitates early resolution of disputes between pioneering and generic manufacturers by treating a Paragraph IV certification as an act of patent infringement. 35 U.S.C § 271(e)(2). A generic manufacturer filing a Paragraph IV certification must provide the patentee and the NDA holder with a detailed basis for its belief that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(2)(B)(i). The patentee has forty-five days to sue the generic manufacturer for infringement. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee does not sue, then the FDA may approve the ANDA. If the patentee sues, then the FDA may not approve the ANDA until expiration of the patent, resolution of the suit, or thirty months after the patentee's receipt of notice, whichever is earlier. 21 U.S.C. §

355(j)(5)(B)(iii). "If the court determines that the patent is not invalid and that infringement would occur, and that therefore the ANDA applicant's paragraph IV certification is incorrect, the patent owner is entitled to an order that FDA approval of the ANDA containing the paragraph IV certification not be effective until the patent expires." Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1245 (Fed. Cir. 2000) (internal citation omitted).

B. The '963 Patent

The application that matured into the '963 patent was filed on September 3, 1993, as a continuation of Serial No. 805,421, which eventually became U.S. Patent No. 5,319,097 ("'097 patent"). (Dkt. entry no. 41, Imbacuan Decl., Ex. 2, '963 patent.) The '963 patent provides a pharmaceutical composition that contains a particular physical form of a hetereocyclic amide derivative, N-[4-[5-(cyclopentyloxycarbonyl)amino-1-methylindol-3-yl-methyl]-3-methoxybenzoyl]-2-methylbenzenesulphonamide ("zafirlukast"), and polyvinylpyrrolidone ("PVP"). Zafirlukast is a compound useful for treating asthma. (Id. at col. 1, lines 38-42.) It exists in more than one physical form, each having different properties. The three forms that have been designated are Form A, Form B, and Form X. (Id. at col. 2, lines 4-9).

Form B and Form X are crystalline and stable, but have relatively poor bioavailability.[2] (Id.) Form A, on the other hand, is amorphous, has relatively good bioavailability, but is unstable and tends to convert into Form B in the presence of water. (Id.) The '963 patent attempts to address the problem of poor stability in Form A while still maintaining good bioavailability. (Id. at col. 2, lines 18-22.) AstraZeneca scientists discovered that combining Form A with PVP as a co-ingredient achieves this objective, declaring in the patent specification that "[s]urprisingly, it has now been found that pharmaceutical compositions meeting these requirements may be obtained by selecting form A as the active ingredient and [PVP] as a co-ingredient." (Id. at col. 2, lines 23-26.) AstraZeneca markets this compound in the United States under the brand name ACCOLATE. (Dkt. entry no. 40, Def. Br. at 2; dkt. entry no. 46, Pl. Opp'n at 1.)

The '963 patent contains two independent claims and six dependent claims; the claims cover actual compositions of the stabilized Form A and a method of administering the compound to treat asthma using the drug. ('963 patent at cols. 10-12.) Claim 1 is representative of the compound AstraZeneca asserts as being infringed and recites the broadest composition:

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[2] Bioavailability denotes "the amount of the active drug absorbed into the bloodstream and available to act on the body." Bayer Schering Pharm. AG v. Barr Labs., Inc., 575 F.3d 1341, 1343 (Fed. Cir. 2009).

> 1. A pharmaceutical composition, which comprises, as the active ingredient, an amorphous physical form of N-[4-[5-(cyclopentyloxycarbonyl)amino-1-methylindol-3-yl-methyl]-3-methoxybenzoyl]-2-methylbenzenesulphonamide, which is substantially free of other physical forms and has an infra-red spectrum (0.5% in KBr) having sharp peaks at 1690, 1530, 1490, 1420, 1155, 1060, 862, and 550 cm^{-1}, and polyvinylpyrrolidone.

('963 patent, cols. 10-11, lines 62-67, 1-2.)

The application for the '963 patent was originally filed as App. No. 116,781 on September 3, 1993. (Pl. Opp'n at 6, Def. Br. at 6.) A patent examiner for the United States Patent and Trademark Office ("PTO") provisionally rejected some of the claims for obviousness-type double patenting as against the copending application for the '097 patent, and all of them for obviousness in view of European Patent ("EP") 199,543. (Imbacuan Decl., Ex. 4, 3-11-94 PTO Office Action at 2-4.) On September 12, 1994, the applicants filed an amendment distinguishing the application from the '097 patent, noting that the '097 patent is primarily directed toward Form B, whereas here the applicants were attempting to patent "a pharmaceutical composition comprising Form A, substantially free of other physical forms, and [PVP]." (Imbacuan Decl., Ex. 5, 9-12-94 Amendment to the '963 patent application ("9-12-94 Amend.") at 5.)[3]

[3] However, the two are related, and it was during prosecution of the '097 parent patent that the applicants noted the "surprising and unexpected results" attributable to PVP. (See Imbacuan Decl., Ex. 10, 11-30-92 Amendment to the '097 patent application ("11-30-92 Amend.") at 5.)

The applicants also attempted to overcome the examiner's concern over the phrase "substantially free of other physical forms," arguing that rather than make the claim redundant with the '097 patent, the phrase explicitly excludes compounds that are substantially Form B, as claimed there. (9-12-94 Amend. at 7.) The applicants reiterated the novelty of the new pharmaceutical compound, requesting the examiner "to indicate where the subject matter of the claim on which the rejection is based provides for an amorphous form of N-[4-[5-(cyclopentyloxycarbonyl)amino-1-methylindol-3-yl-methyl]-3-methoxybenzoyl]-2-methylbenzenesulphonamide, substantially free of other physical forms which has an infra-red spectrum (0.5% in KBr) having sharp peaks at 1690, 1530, 1490, 1420, 1155, 1060, 862, and 550 cm^{-1}, containing polyvinylpyrrolidone, as instantly claimed. Absent such a showing, the present claims . . . are not obvious in view of the patented invention . . . ." (Id. (emphasis in original).)

The applicants then addressed the obviousness rejection in light of EP 199,543. First, the applicants argued that "the disclosure of the cited reference teaches literally millions of compounds in conjunction with six examples of pharmaceutical dosage forms." (Id. at 8.) The applicants conceded that Form A was among the eighteen preferred compounds in the cited reference, but argued:

i) There is no teaching or suggestion that the compound of Example 105 should be selected;
ii) There is no teaching or suggestion that the compounds of Example 105 exists in various physical forms;
iii) There is no suggestion that of such physical forms, should they exist, the amorphous form should be selected; and
iv) There is no teaching or suggestion that if the amorphous form is selected, the one pharmaceutical dosage form incorporating PVP should also be selected for use in conjunction therewith.

(Id. (emphasis added).) The applicants continued "even if the appropriate multiple selections were made from the prior art, there is no basis . . . for any expectation that the resulting pharmaceutical composition would provide [the desired effects]. Accordingly, the presently claimed composition, at best, would be a fortuitous selection . . . unexpectedly yielding superior properties not suggested by the cited prior art." (Id. at 9.)

The examiner finally allowed claim 2, claim 19, and claim 20. (Dkt. entry no. 45, Parrett Decl., Ex. 6 at 55.) The rejection of the claims over EP 199,543 were withdrawn "since the specific physical form of this compound is not disclosed by the prior art. Further, the data of the specification herein provide evidence of unexpected results obtained from the specific physical form claimed herein." (Id. at 58.) The '963 patent issued on January 9, 1996. ('963 patent.)

C. Dr. Reddy's ANDA

The accused compound here is Dr. Reddy's Zafirlukast Tablets. As the formulation described in the '963 patent, the

accused compound contains Form A (amorphous zafirlukast) and a binder that stabilizes Form A, preventing it from converting to Form B or Form X. However, in contrast to AstraZeneca's formulation in the '963 patent, the accused compound does not use PVP as its binder and stabilizer. Rather, the accused tablet utilizes a different binder, Hydroxypropyl Cellulose NF ("HPC").

Dr. Reddy's submitted an ANDA to the FDA on February 7, 2008, seeking approval for a product that is bioequivalent to AstraZeneca's ACCOLATE product. (Imbacuan Decl., Ex. 11, Dr. Reddy's ANDA.) Dr. Reddy's ANDA contains a formulation for Zafirlukast Tablets, dosage form 10 mg and 20 mg, containing amorphous zafirlukast. With its ANDA, Dr. Reddy's filed a Quality Overall Summary ("QOS"). The QOS described the chemical structure, manufacturing process, and possible impurities for its Zafirlukast Tablets. According to the QOS, the Zafirlukast Tablets contained, among other ingredients, amorphous zafirlukast and HPC as a binder. (Dr. Reddy's ANDA at 001444.) The QOS attested to the stability of the amorphous zafirlukast in its formulation, even in the absence of PVP. (Id. at 001451.)

Dr. Reddy's, as required by 21 U.S.C. § 505(j)(2)(B)(ii), notified AstraZeneca of its ANDA and its Paragraph IV certification in which it asserts that the Zafirlukast Tablets do not infringe the '963 patent, noting that binder HPC was beyond the reach of the '963 patent claiming PVP. (Dkt. entry no. 1,

Compl. at par. 15; dkt. entry no. 7, Ans. at par. 15.)[4] It is undisputed that the accused compound does not literally infringe the claims. (Dkt. entry no. 59, 9-28-10 Tr. ("Tr.") at 5.) It is also undisputed here that Dr. Reddy's compound is equivalent to the '963 patent under the doctrine of equivalents. (Id. at 49-50.) The only issue before the Court is whether AstraZeneca is barred from asserting infringement under the doctrine of equivalents by way of argument-based prosecution history estoppel.

D. Procedural History

AstraZeneca filed the Complaint against Dr. Reddy's, asserting infringement of U.S. Patent No. 6,143,775 ("'775 patent"), the '097 patent, and the '963 patent on June 27, 2008. (See Compl.) After Dr. Reddy's amended its ANDA in September 2008, committing to using a different manufacturing process to avoid the '097 patent and the '775 patent, the parties agreed to the dismissal of Count I and Count II of the Complaint, which alleged infringement of the '097 patent and the '775 patent, as well as Dr. Reddy's first and second counterclaims for declaratory judgments of noninfringement and invalidity of the same. (Dkt. entry no. 31, 6-12-09 Stipulation and Order.)

[4] The Complaint states that Dr. Reddy's notice claims to have accomplished this, and the answer admits as much. Though the Court does not have these documents, neither party has disputed their actual existence.

However, Count III and the third counterclaim involving the '963 patent remained. Dr. Reddy's moved for summary judgment of noninfringement and AstraZeneca cross-moved for summary judgment on the issue of prosecution history estoppel. (Dkt. entry no. 38, Def. Mot.; dkt. entry no. 49, Pl. Cross-Mot.) Oral argument was heard on September 28, 2010. (Dkt. entry no. 58.)[5]

II. Discussion

A. Standard for Summary Judgment on Infringement

A motion for summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c)(2). Summary judgment is therefore appropriate when there is no genuine issue of material fact or when, drawing all factual inferences in favor of the nonmoving party, no "reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The party opposing the motion cannot rest on the mere allegations or denials of its pleading, but must "go beyond the pleadings and by her own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file' designate 'specific facts showing that there is a genuine issue

[5] The parties have also briefed the Court on claim construction (dkt. entry nos. 29-30, 33-34), but that is not at issue here. (Tr. at 46.)

for trial.'" Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986) (citation omitted). Material facts are those which "might affect the outcome of the suit under the governing law." Anderson, 477 U.S. at 248. Any doubt as to the existence of any issue of material fact requires denial of the motion. Id.

Determination of a claim of infringement involves a two-step inquiry. First, the patent claim is construed, a question of law in which the scope of the asserted claim is defined. See Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56 (Fed. Cir. 1998). Second, the claim, as construed, is compared to the accused compound. See id. This is a question of fact. See Insituform Techs., Inc. v. Cat Contracting, Inc., 161 F.3d 688, 692 (Fed. Cir. 1998) (citing SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1125 (Fed. Cir. 1985)). To prevail, the party asserting infringement must establish by a preponderance of the evidence that the accused compound infringes one or more claims of the patent either literally or under the doctrine of equivalents ("DOE"). See id.

The construction of the claim at issue in the '963 patent is not in dispute. (Def. Br. at 12; Tr. at 46.) AstraZeneca does not assert literal infringement of the '963 patent here, because Dr. Reddy's compound contains HPC instead of PVP, but AstraZeneca does assert infringement under the DOE. (Pl. Opp'n at 1-2.) Dr. Reddy's concedes here that HPC is equivalent to PVP. (Def. Br.

at 1.) However, Dr. Reddy's argues that prosecution history estoppel bars AstraZeneca from asserting infringement under the DOE. Thus, the Court need only address the issue of whether AstraZeneca may assert infringement under the DOE or whether prosecution history estoppel bars such an assertion.

"If patents were always interpreted by their literal terms, their value would be greatly diminished. Unimportant and insubstantial substitutes for certain elements could defeat the patent, and its value to inventors could be destroyed by simple acts of copying. . . . The scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd., 535 U.S. 722, 731-32 (2002) (citing Winans v. Denmead, 56 U.S. (15 How.) 330, 347 (1854)). Thus, even if "a product or process . . . does not literally infringe upon the express terms of a patent claim[, it] may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997).

The patent monopoly, however, is "a property right; and like any property right, its boundaries should be clear. This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he

owns, and the public should know what he does not." Festo, 535 U.S. at 730-31 (2002). Thus, the Court will look to the doctrine of prosecution history estoppel ("PHE") to act as a limit on the scope of patent available to a claimant under the DOE. Bayer, 212 F.3d at 1251. "[PHE] limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of the patent." PODS, Inc. v. Porta Stor, Inc., 484 F.3d 1359, 1367 (Fed. Cir. 2007) (citing Southwall Techs. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed. Cir. 1995)). While infringement under the DOE is a question of fact, the applicability of PHE is a question of law. See Bayer, 212 F.3d at 1251.

B. Argument-Based Prosecution History Estoppel

> Prosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process. Estoppel is a "rule of patent construction" that ensures that claims are interpreted by reference to those that have been cancelled or rejected. . . . When, however, the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent.

Festo, 535 U.S. at 733-34 (internal citations omitted). PHE can be triggered during prosecution in one of two ways, "either (1) by making a narrowing amendment to the claim ('amendment-based estoppel') or (2) by surrendering claim scope through argument to the patent examiner ('argument-based estoppel')." Conoco, Inc.

v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1363 (Fed. Cir. 2006). Amendment-based PHE is not at issue here, but Dr. Reddy's asserts argument-based PHE against AstraZeneca's claim of infringement under the DOE. (Def. Br. at 14.)

"To invoke argument-based estoppel, the prosecution history must evince a 'clear an unmistakable surrender of subject matter.'" Eagle Comtronics, Inc. v. Arrow Commc'n Labs., Inc., 305 F.3d 1303, 1316 (Fed. Cir. 2002) (internal citations omitted). "In determining whether there has been a clear and unmistakable surrender of subject matter, the prosecution history must be examined as a whole." Bayer, 212 F.3d at 1252. "Any argument-based estoppel affecting a limitation in one claim extends to all claims in which that limitation appears." Eagle, 305 F.3d at 1316. Even if an assertion in support of patentability is not necessary to secure allowance of a claim, "a statement may operate to preclude the patentee from claiming otherwise in an infringement suit." Forest Labs., Inc. v. Abbott Labs., 239 F.3d 1301, 1314 (Fed. Cir. 2001). "The relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." Conoco, 460 F.3d at 1364.

C. Analysis

Dr. Reddy's argues that PHE applies because it is not suggested in the prosecution history that any binder other than

PVP, including HPC, would stabilize Form A while providing good bioavailability. (Tr. at 8.) Dr. Reddy's claims AstraZeneca could have provided PVP binder alternatives in the patent if there were possible equivalents. (Def. Br. at 20.) For example, it argues, textbooks list common "binders and adhesives," which include PVP, cellulose derivatives (including HPC), gelatin, and starch. (Imbacuan Dec., Ex. 13, L. Lachman et al., The Theory and Practice of Industrial Pharmacy 321, 327 (3d ed. 1986) ("Industrial Pharmacy").) Dr. Reddy's asserts AstraZeneca did not disclose or suggest any of these other binders, and was indeed only able to obtain the '963 patent upon demonstrating the surprising and unexpected results from specifically using PVP. (Tr. at 18.) Moreover, Dr. Reddy's notes, AstraZeneca listed alternatives for other excipient components of the invention, including carriers and processing adjuvants. (Tr. at 11; '963 patent, cols. 2-3.) At the same time, Dr. Reddy's argues, the inventors did not point to any excipient that might perform similar functions to PVP, just to PVP itself. (Def. Br. at 7.)

AstraZeneca, on the other hand, argues the inventors did not clearly and unmistakably surrender equivalents because they did not state they were surrendering equivalent binders, that PVP was the only, critical, or essential way to accomplish the invention,

or that other binders did not work. (Tr. at 50.)[6] AstraZeneca claims it is notable that the inventors did not argue PVP had unique properties distinguishing it from equivalent polymers. (Pl. Opp'n at 9.)

A number of cases have examined what language can constitute argument-based PHE. In many cases, the Federal Circuit has held that in arguing against rejection, while one may surrender what the invention is being differentiated from, one does not necessarily surrender all other equivalents, especially when the applicant does not discuss or limit the contents of the claimed invention itself. See, e.g., Conoco, 460 F.3d at 1364 (in overcoming obviousness, patentee surrendered metal stearates in stressing the "criticalities of using fatty acid wax" instead, but did not clearly surrender other fatty acid wax equivalents); AquaTex Indus., Inc. v. Techniche Solutions, 419 F.3d 1374, 1382-83 (Fed. Cir. 2005) (no PHE because when patentee argued the prior art did not suggest "fiberfill batting and polymeric fibers and/or particles of the composite material" in its invention, it did not discuss the composition of the fiberfill batting itself); see also Bos. Scientific Scimed, Inc. v. Cordis Corp., No. 03-

[6] AstraZeneca also argues as an initial matter that Dr. Reddy's may not rely on PHE because it failed to raise the issue in its initial ANDA notice letter or in its Answer to the Complaint. (Pl. Opp'n at 13; Tr. at 31.) The Court rejects this argument because PHE may not be pleaded as an affirmative defense and only becomes applicable when the DOE has been raised. PB Farradyne, Inc. v. Peterson, No. 05-3447, 2006 WL 132182, at *4 (N.D. Cal. Jan. 17, 2006).

283, 2005 WL 1322974, at *3 (D. Del. June 3, 2005) (argument that patentee's invention was "a stent with an elastomeric coating" was simply an explanation that it was not "a coating of crystalline, nonelastomeric material," and thus did not surrender equivalents to other "elastomeric" coatings).

The cases that have found argument-based PHE often do so where the applicant has specifically disclaimed an aspect or feature found in the prior art. For example, in Spine Solutions v. Medtronic Sofamor Danek USA, Inc., 620 F.3d 1305, 1317 (Fed. Cir. 2010), the patentee claiming an invention with a single anchor surrendered devices having two anchors, because during prosecution it distinguished a prior art reference by arguing "a reference disclosing two anchors does not disclose a device affirmatively claiming a single anchor."

The Federal Circuit has also applied PHE where the applicant emphasizes particular locations or features above others. In Medtronic Navigation, Inc. v. Brainlab Medizinische Computersystems GMBH, 417 F.Supp.2d 1188, 1194 (D. Colo. 2006), aff'd, 222 Fed.Appx. 952 (Fed. Cir. 2007), the court held that a competing navigational surgeon would reasonably believe that the patentee was "limiting the claim to require the activation of emitters on the probe and the patient," and thus surrendering the equivalent placement of similar beacons on the "camera housing and . . . surgical tools." See also Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1327 (Fed. Cir. 2003) (where patentee

surrendered claim scope around an invention that visibly outlines an energy zone by "insisting that [it] directs energy in a way that does not affect temperature measurement").[7] Similarly, in Bayer, the patentee was estopped from asserting equivalence when it "emphasized the inventive nature of its claimed SSA range and the disadvantages of the SSAs outside its claimed range" during prosecution. 212 F.3d at 1254.

Patentees need not, however, stress the disadvantages of other equivalents to clearly and unmistakably surrender them. Most applicable here are the Federal Circuit cases that found clear and unmistakable surrender when the patentee asserted the singularity or uniqueness of the claimed invention in arguing for its patentability. In Forest, the patentee had argued that "only" the listed compound had the "particular and novel" property that enabled the invention claimed. 239 F.3d at 1313-14. The court held this statement was "an unmistakable assertion made to the PTO in support of patentability" and even if it is unnecessary to secure the patent, "such a statement may operate to preclude the patentee from claiming otherwise in an infringement suit." Id. More recently, the court held a patentee had clearly and unmistakably limited its claims to a "singular rectangular-shaped frame" when it argued the shape in

[7] While Omega involved the issue of prosecution disclaimer, the same "clear and unmistakable" standard required in argument-based PHE to show the disavowal of claim scope during prosecution also applies. Omega, 334 F.3d at 1326 n.1.

support of patentability during prosecution, and thus had "surrendered any claim to a frame that was not rectangular or four-sided." PODS, 484 F.3d at 1368 (emphasis added).

The Court concludes here that a competitor looking at the prosecution history as a whole would reasonably believe that AstraZeneca clearly and unmistakably surrendered binders other than PVP. First, during prosecution, the applicants argued against an obviousness rejection from the PTO by stating that:

> [s]urprisingly, it has been found that this problem [the conversion of Form A into Form B] can be solved by incorporating [PVP] into the formulation. Thus [PVP] has unexpectedly been found to be capable of stabilizing form A in the presence of water.

(11-30-92 Amend. at 5.) Moreover, "the bioavailability of the compound when administered to humans in composition according to the invention is surprisingly greater than when it administered in a composition prepared without PVP." (Id.)[8] The applicants were pointing out a surprising, and apparently unknown, feature of PVP, which is otherwise a commonly known binder. (Industrial Pharmacy at 321.) See Colgate Palmolive Co. v. W.L. Gore & Assocs., Inc., 919 F.Supp. 767, 774 (D.N.J. 1996) (where the status of an accused equivalent as being commercially known when patent application was argued contributed to its surrender).

[8] Though this argument came during prosecution of the parent application upon which the patent at issue is based, it is relevant because they share the same specification.

AstraZeneca argues the contention in the specification that a compound "surprisingly . . . may be obtained" with a particular formula is not a "statement of exclusion" that surrenders other binders. (Tr. at 41.) Instead, AstraZeneca points to the patent examiner's allowance of the patent on the grounds that "the specific physical form of this compound is not disclosed by the prior art" and "the data of the specification herein provide evidence of unexpected results obtained from the specific physical form claimed herein," and asserts the examiner must have meant "the physical form" to mean simply "Form A." (Tr. at 42-44; see also Parrett Decl., Ex. 6 at 4 (discussing why the examiner withdrew the rejection of the '963 patent over EP 199,543).) However, what the specification of the '963 patent states is that "[s]urprisngly, it has been found that pharmaceutical compositions meeting these requirements may be obtained by selecting form A as the active ingredient and [PVP] as a co-ingredient," specifically. ('963 patent, col. 2, lines 23-26 (emphasis added).) Moreover, to the extent a decision is necessary, the Court is persuaded by the examiner's additional reference to the testing that showed the "form" was stable. (Parrett Decl., Ex. 6 at 4.) Because it took the addition of PVP to make the compound stable, this indicates "the physical form" must mean "Form A with PVP."

The applicants also argued against the examiner's assertion that the invention was suggested by the prior art by pointing out that:

> there is no suggestion or motivation in the art that would lead one to make the particular combination of components of the presently claimed pharmaceutical composition . . . there is no basis whatever in the prior art for any expectation that the resulting pharmaceutical composition would provide . . . relatively good bioavailability together with sufficient stability.

(9-12-94 Amend. at 9 (emphasis added).) This indicates that it was the PVP in their formulation of amorphous zafirlukast that made it patentable, as it was the PVP that provided the "surprisingly" sufficient stability. Indeed, the applicants distinguished the '963 patent from the '097 patent by emphasizing that the compound claims in '097 were "substantially all form B" whereas the claims of '963 comprise "form A substantially free of other physical forms and PVP." (9-12-94 Amend. at 6-7 (emphasis added).)

Perhaps most importantly, the applicants argued that "there is no teaching or suggestion that if the amorphous form is selected, the one pharmaceutical dosage form incorporating PVP should also be selected for use in conjunction therewith." (9-12-94 Amend. at 8 (emphasis added).) While AstraZeneca argues that it did not use the words "critical" or "essential" in its application, and it did not say there is no other way to accomplish the invention (Tr. at 35, 41), the law does not

require these specific words. See PODS, Inc., 484 F.3d at 1368 (where "[a] competitor would reasonably believe that PODS had surrendered any claim to a frame that was not rectangular" because that was how the applicant described the invention). In our view, the emphasis on the surprising and unexpected action in the one dosage where PVP is included as a co-ingredient clearly and unmistakably indicates to a competitor that other equivalent binders are surrendered. See Forest, 239 F.3d at 1314 (where the applicant argued "[t]he results obtained are caused by the particular and novel surface-active agent isolated"); Colgate, 919 F.Supp. at 773 (where applicant "represented by negative implication that all other non-microcrystalline waxes, including beeswax, would not bind to PTFE").

AstraZeneca additionally provided the results of testing on Form B, Form X, and Form A with and without PVP. ('963 patent, cols. 8-10.) Although AstraZeneca contends the inventors made no "statement attesting to the unique advantages of PVP as opposed to other polymers," in testing Form A without PVP they used a different commonly known binder, a "pregelatinized starch." (Pl. Opp'n at 20; '963 patent, cols. 8-10.) The results showed the formulation without PVP had a much lower bioavailability. ('963 patent, cols. 9-10.) Basing the proof of "improved stability" and "superior bioavailability" of the invention on this comparative example of Form A with a different binder further

supports the conclusion that AstraZeneca ceded the field of other binders from the patent. ('963 patent, cols. 8-10.) See Isham v. Pillotex Corp., 91 F.Supp.2d 992, 999 (E.D. Tex. 2000) (where applicant's statement that a "total panel concept was unsuccessful" surrendered other equivalent structures with "stretch panels on all sides").

We have considered two district court cases that might seem to undermine this conclusion, but we find them unpersuasive in the circumstances here. First, in Virkler v. Herbert Enters. Inc., 403 F.Supp.2d 1141, 1144, 1150 (M.D. Fla. 2005), the pro se patentee did not clearly and unmistakably surrender different sizes of handles despite arguing that handles "less that 4 inches . . . would be too small," because the patentee included language warning competitors that her examples were just illustrative, and because she "made clear that the reason she had described her patent with those dimensions was so that a faucet would fit into the handle." In contrast here, no such warning language or clarification surrounding the selection of PVP is present in the '963 patent. Second, the court in Schwarz Pharma, Inc. v. Paddock Labs., Inc. held there was no argument-based PHE where, although the applicant argued "an alkali or alkaline earth metal carbonate was one of the 'two necessary ingredients,'" the applicant did not make arguments "with respect to potential equivalents to an alkali or alkaline earth metal carbonate and

whether or not they would be less desirable or unworkable." No. 05-832, 2006 WL 3004200, at *5 (D. Minn. Oct. 20, 2006). This is similar to AstraZeneca's argument above, but while the Schwarz applicant merely used the word "necessary," the applicants here used the words "surprising" and "unexpected" in reference to the singular "one pharmaceutical dosage form incorporating PVP," to the implied exclusion of all others. See Forest, 239 F.3d at 1314.

III. CONCLUSION

The Court holds that Dr. Reddy's Zafirlukast Tablets do not infringe the '963 patent. According to the doctrine of prosecution history estoppel, AstraZeneca is precluded from asserting infringement under the doctrine of equivalents over the formulation of amorphous zafirlukast specified in Dr. Reddy's ANDA because the prosecution history of the '963 patent indicates that AstraZeneca surrendered equivalents to PVP. Therefore, the Court will grant Dr. Reddy's motion for summary judgment of noninfringement, and deny AstraZeneca's cross-motion for summary judgment on the issue of prosecution history estoppel. The Court will issue an appropriate order and judgment.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: November 15, 2010